

Appl. No. : 10/636,163  
Filed : August 7, 2003

### REMARKS

In response to the Office Action mailed September 15, 2004, Applicant respectfully requests the Examiner to reconsider the above-captioned application in view of the foregoing amendments and the following comments. As a result of the amendments listed above, Claims 1-13 are now pending. Claims 1-4, 7, and 9-11 have been amended and new Claims 12 and 13 have been added.

#### Summary of Office Action

The Office Action rejected Claims 1-11 under the judicially created doctrine of obviousness-type double patenting over Claims 1-8 of U.S. Patent No. 6,695,817, and rejected Claims 1, 5-6, and 9 under 35 U.S.C. § 102(e) as being anticipated by Jepson et al. (Jepson) (Patent Number 5,797,897) or Lynn et al. (Lynn) (Patent Number 6,171,287). Finally, the Examiner indicated allowable subject matter in Claims 2-4, 7-8, and 10-11.

#### Rejection For Obviousness-Type Double Patenting

The Office Action rejected Claims 1-11 under the non-statutory, obviousness-type double patenting.<sup>1</sup> In order to expedite allowance of the present application, Applicant has attached an appropriate Terminal Disclaimer. Accordingly, Applicant respectfully requests withdrawal of the non-statutory, obviousness-type double patenting rejection of Claims 1-11.

#### Rejections Under 35 U.S.C. § 102(e) - Jepson

The Office Action rejected Claims 1, 5-6, and 9 under 35 U.S.C. § 102(e) as being anticipated by Jepson. Of these, only Claim 1 is independent. Applicant respectfully submits that these rejections should be withdrawn. Jepson fails to teach or suggest all of the elements of the claims as amended. See M.P.E.P. § 2131 (stating that in order to anticipate a claim, a prior art reference must teach every element of the claim).

For example, Applicant respectfully submits that Jepson fails to teach or suggest the recited features of the seal element in amended Claim 1. Figure 3 of Jepson is exemplary of Jepson's disclosed septum, but it differs from the other septums disclosed in Jepson in that the opening 66 in Figure 3 appears to run through the entirety of septum 52. In the other variations in Jepson, the opening runs part way or does not exist at all (Figures 16 and 20 show these alternatives).

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<sup>1</sup> By rebutting the Examiner's rejections, Applicant does not concede that any of the cited references are proper prior art references.

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Jepson does not disclose or suggest “the passage being relatively wide in the region of the upstream end of the seal element and the passage being relatively narrow in the region of the second end of the housing,” as recited in Claim 1. The figures and text cited in Jepson disclose a septum having a slit. The passage created by that slit is not defined in Jepson. Jepson fails to teach or disclose the above recited language regarding the passage in the seal element.

Furthermore, Jepson does not disclose a “passage adapted to have a relatively small interior volume when in an undisturbed state and a larger interior volume upon the introduction of the second medical device into the upstream end of the passage, the passage adapted to retract to define a restricted flow path and a relatively small interior volume upon the withdrawal of the second medical device from the seal element,” as recited in Claim 1. Nor does Jepson disclose a passage adapted to retract “so that a fluid occupying the interior volume is forced toward the downstream end as the passage retracts,” as recited in Claim 1. Moreover, Jepson does not disclose a passage comprising “a neck portion positioned in a region near the upstream end,” as recited in Claim 1.

For at least these reasons, Jepson fails to disclose or suggest the invention recited in Claim 1. Accordingly, Applicant respectfully submits that the rejections over Jepson should be withdrawn. Additionally, Applicant submits that the foregoing rejections should not be applied to dependent Claims 2-11 because of their dependency on Claim 1, and because of the additional features recited therein.

**Rejections Under 35 U.S.C. § 102(e) - Lynn**

The Office Action also rejected Claims 1, 5-6, and 9 under 35 U.S.C. § 102(e) as being anticipated by Lynn. Applicant respectfully submits that these rejections should be withdrawn. Lynn, like Jepson, fails to teach or suggest all of the elements of these claims as amended.

Lynn discloses a number of different septum configurations. The Examiner cited Figure 1 and col. 18, lines 12-67 and column 19, lines 1-35 as disclosing Applicant’s seal element with passage. However, nowhere in the cited text or figure does Lynn disclose the claimed medical valve. Neither Figure 1 nor the cited text shows or describes the cross section of the seal element and thus Lynn does not indicate the design of the passage within that seal element.

Applicant does note that Figures 41 and 42 illustrate a cross-sectional view of the Lynn septums. These figures are described in the specification:

Slit 642 may have a substantially uniform slit width along the entire length thereof through septum 634. As an alternative, as illustrated in FIG. 41, the septum 642' reduces in width as a tapered step, *so that the slit has its greatest width adjacent the septum upper portion 636'* and then in the distal septum portion 672' there is a stepped reduction in width of septum slit 642', to a minimum width in duckbill portion 643'. *This stepped reduction in slit width allows a wide luer taper to penetrate far enough to open the slit for fluid flow into Y-site passage 620*, while still sealing on the shaft of a smaller blunt cannula which completely penetrates the septum. As shown, the slit 642' is preferably incomplete, having a residual membrane 671' which is ruptured when the slit 642' is opened by insertion of the luer tip.

FIG. 42 shows an alternate slit width reduction configuration in which slit 642'' is tapered along approximately one half its length. *As with the embodiment of FIG. 41, the slit 642' has its greatest width adjacent the septum upper portion 636'* and then in extension 640' there begins a gradual reduction in width that continues through lower portion 672', to a minimum width in duckbill portion 643'. This tapered reduction in slit width also allows a wide luer taper to penetrate far enough to open the slit for fluid flow into Y-site passage 620 while still sealing on the shaft of a smaller blunt cannula which completely penetrates the septum. Again, the slit 642' is preferably initially incomplete as shown at 671'.

Lynn at 21:1-28 (emphasis added). Neither the figures nor their description teaches or discloses a seal element with a passage comprising "a neck portion positioned in a region near the upstream end," as recited in Claim 1. In fact, as emphasized above, Lynn teaches away from the recited element by noting that the width of the septum slit and its subsequent stepped or gradual reduction in width are designed to allow "a wide luer taper to penetrate far enough to open the slit for fluid flow into Y-site passage." *Id.* Lynn does not disclose or suggest a neck portion in the region of the upstream end as recited in amended Claim 1.

Accordingly, Applicant respectfully submits that the foregoing rejections over Lynn should be withdrawn. Additionally, Applicant submits that the foregoing rejections should not be applied to dependent Claims 2-11 because of their dependency on Claim 1, and because of the additional features recited therein.

#### **New Claims 12 and 13**

New Claims 12 and 13 have been added to more specifically recite certain embodiments of Applicant's inventions. Applicant respectfully submits that new Claims 12 and 13 are allowable because of their dependency on Claim 1, and because of the additional features recited therein.

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CONCLUSION

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims. Accordingly, Applicant requests a Notice of Allowance.

If any issues require clarification, the Examiner is respectfully requested to call the undersigned attorney to expedite allowance of this application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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